IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' AMENDED MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D

Defendants have yet again attacked Dr. Daniel S. Elliott's opinions in a random and chaotic fashion. These attacks are not only similar to the arguments made by the Defendants in the *Bellew v. Ethicon* bellwether trial, where this Court found Dr. Elliott to be qualified and permitted to testify, but also nearly identical to the arguments they made in the *Mullins v. Ethicon* briefing which is pending before this Court – with many portions remaining exactly the same. This Court has already addressed and rejected most of Defendants' arguments and should reject them again.

Dr. Elliott's opinions are based on his extensive experience and substantial literature study on myriad types and brands of transvaginal mesh. As this Court previously concluded when allowing Dr. Elliott to testify:

> Dr. Elliott has personally treated patients with Prolift mesh complications "too numerous to count." (Elliott Dep. [Docket 116-2], at 178). He has published nearly 60 peer-reviewed articles and given over 100 lectures pertaining to POP. (Elliott Report [Docket 116-1], at 2). Additionally, he has published two scientific manuscripts dealing specifically with polypropylene mesh. (*Id.*). According to Dr. Elliott, his "practice has become increasingly dedicated to treating a whole host of life-altering complications associated with the use of both SUI and POP meshes, including meshes made by Ethicon."

Bellew v. Ethicon, Inc., No. 13-cv-22473, Mem. Op. & Order, Dkt. No. 265, at pp. 23 (Nov. 20, 2014). In prior rulings, this Court rejected the same and similar arguments as the Defendants have brought forth here - and the Court should do the same with this Motion to Exclude.

BACKGROUND

Dr. Daniel S. Elliott is an associate professor of urology in the section of Female Urology and Reconstructive Surgery at the Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. (Ex. 1 at 1).[1] He has treated hundreds of patients with mesh-related complications. (Ex. 2 at 2). For 15 years, he has specialized in treating urinary incontinence in women. (Ex. 1 at 1). He has delivered numerous lectures on treatment options for stress urinary incontinence (SUI) in women, including the limitations of each. (Ex. 1 at 3). He is an editor or reviewer for 15 urologic and gynecologic journals and has reviewed all readily available medical literature on SUI treatment options. He has also reviewed an extensive number of internal Ethicon documents and depositions of its personnel in developing his opinions in these cases. (Ex.1 at 4).

Dr. Elliott has extensive experience implanting both naturally made and synthetic slings to treat SUI, including polypropylene slings. In fact, synthetic slings were his primary treatment for SUI prior to August, 2013. (Ex. 3 at 26:25-27:10; 27:14-25; 48:16-20). He implanted several hundred synthetic slings during that time period. (Ex. 3 at 30:2-15 48:16-20).

ARGUMENT

Counting sub-parts, Defendants have 17 different arguments for limiting Dr. Elliott's testimony. Plaintiffs will respond point-by-point, as best it can be done in the space available.

I. Dr. Elliott's Testimony Regarding the Superiority of Traditional Slings Should Be the Subject of Case Specific Summary Judgment Motions, Not *Daubert*.

Defendants first argue that Dr. Elliott should be prevented from offering his opinions that traditional treatments for SUI are safer alternatives to their mesh products because traditional SUI treatments are not "medical devices" and, therefore cannot legally qualify as "safer alternative designs." This argument is not properly the subject of a *Daubert* Motion. It is instead a legal argument that should be raised in a motion for summary judgment. Particularly

[1] Dr. Elliott's TVTR report in these cases is Exhibit 1 and his Prolift report is Exhibit 2. Dr. Elliott's deposition transcript in the *Mullins* case is Exhibit 3. The memorandum supporting Defendants' motion is "Memo."

because, as Defendants set forth in their footnote 2, there are multiple state laws that need to be addressed to properly analyze this issue.[2]

Defendants attempt to argue there can be no question of fact on this issue – clearly a summary judgment standard – because Dr. Elliott has "admitted" that traditional repairs are not "medical devices." Memo at 3 ("Dr. Elliott has acknowledged that autologous slings and the Burch procedure are not medical devices."). Dr. Elliott, of course, made no such statement. Dr. Elliott simply stated the obvious – traditional repairs, such as autologous slings, are not *permanent* implants and, are instead, resorbed by the body over time. This distinction does not equate to an admission that, as a matter of legal interpretation, traditional repairs are not safer alternatives.

The autologous PVS sling involves acquiring tissue from a woman's abdominal wall, shaping it into a sling and implanting it around the neck of the bladder. (Ex. 1 at 8). The natural sling is absorbed by the body. (Ex. 3 at 73:1-74:4; 75:17-76:11). The Burch procedure involves using a series of sutures to attach the neck of the bladder to the pubic bone. (Ex. 1 at 8). Dr. Elliott distinguished the products involved in these procedures (sutures and medical grade fascia) from the medical "devices" Defendants sell (a synthetic sling) on two grounds. First, the PVS is harvested from the patient herself rather than being "man-made" outside of the body. (Ex. 3 at 23:14-20). Second, but significantly, throughout his deposition Dr. Elliott noted that the autologous sling differs from synthetic mesh because it is not "permanent." In particular, Dr. Elliott repeatedly distinguishes Defendants' products as "permanent" devices. He clearly states that Defendants' TVT is an "implantable permanent medical device." (Ex. 3 at 70:3-14). Dr.

[2] For example, this Court has previously determined that West Virginia law does not require proof of a safer alternative design for a plaintiff to prevail on a design defect cause of action. *Mullins v. Ethicon, Inc.*, Civ. Act. No. 2:12-cv-02952, 2015 WL 4635573, at *9 (S.D. W. Va. Aug. 4, 2015) (*citing Keffer v. Wyeth*, 791 F. Supp. 2d 539, 547048 (S.D.W. Va. 2011)). Moreover, as Defendants' admit, even if the Court were to grant such a Motion, it simply creates a jury question on the issue of safer alternative design. *See* Memo at 2 (citing *Hines v. Wyeth*, 2011 WL 1990496 (S.D.W. Va. May 23, 2011).

Elliott testifies that comparison of complications between synthetic mid-urethral slings to autologous PVS is challenging because "it's comparing apples to oranges because there is no medical device placed in those patients that's permanent." (Ex. 3 at 93:14-21). "As I've mentioned before, pubovaginal slings and Burch are not a permanent medical device that's implanted in a woman." (Ex. 3 at 103:15-22). As discussed below, it is the permanence of artificial slings that make determining complications difficult – complications can arise for years, even decades, after implantation.

Moreover, the "artificial" versus "natural" distinction was addressed in *Hines v. Wyeth*, Civ. Act. No. 2:04-0690, 2011 WL 1990496 (S.D. W. Va. May 23, 2011) (*cited in* Memo at 2). *Hines*, like here, involved a claim by the plaintiff that a natural pharmaceutical product was a safer alternative design to a synthetic product. As in this case, the defendant in *Hines* cited multiple significant differences in the composition and use of the products. But the court in *Hines* determined, as Defendants acknowledge, that whether the natural product was a viable alternative design to the synthetic product was one for the jury, not the judge, to make. *Id.* at *9. In so holding, the court distinguished the other principal case on which Defendants rely – *Theriot v. Danek Med., Inc.*, 168 F.3d 253 (5th Cir. 1999). The court noted that in *Theriot*, the plaintiff had impugned all pedicle screws and thus was attacking the doctor's choice of treatment options, rather than the determination of whether to use a synthetic or natural product. *Hines*, 2011 WL 1990496 at *9 (*citing Theriot*, 168 F.3d at 256).

Therefore, even if the Court were to reach the question of safer alternative design in the context of a *Daubert* Motion – which it should not – Dr. Elliott has considered and explained why traditional repairs satisfy the criteria of a safer alternative. Even assuming the involvement of a "device" were required in order to be considered a safer alternative, the safer treatments Dr. Elliott recommends do involve sutures and/or slings – just not the weaved mesh made by Defendants. It is this mesh component that makes these procedures unsafe. On all aspects of this

issue, Defendants' arguments fail and their Motion should be denied.

II. The Methods Employed By Dr. Elliott In Reaching His Opinions Were Reliable.

Defendants claim Dr. Elliott is unqualified to discuss their product because he refuses to absolutely quantify its complication rate. (Memo at 4). Additionally, Defendants contend that Dr. Elliott ignored findings by the American Urological Association (AUA), the American Urogynecology Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU), as well as the Cochrane Review. (Memo at 4-7). They also claim Dr. Elliott cherry-picked studies and selectively considered data. (Memo at 7). However, Dr. Elliott has reviewed, analyzed and discussed in great detail all of the relevant scientific evidence in reaching his opinions that Defendants' devices are unsafe.

A. Dr. Elliott explained and supported his concerns with complication rates.

While it is true that Dr. Elliott does not attempt to precisely quantify the complication rate associated with the TVT, he explains in painstaking detail the inability of existing studies to provide precise estimates of complications. The studies examining these complications do not even purport to study the effect of the product in the long-term, thus no precise quantification is available. (Ex. 3 at 110:13-17; 196:1-14). Even the studies that Defendants erroneously claim are long-term do not encompass much of the patient's remaining life, which is the relevant benchmark for a product that will remain in the body forever. (Ex. 3 at 128:10-129:10). Many complications do not occur until *years* after implantation. (Ex. 3 at 204:2-13; 210:9-20). So, while it is clear that polypropylene meshes, including TVT, have more complications than alternative treatments, no scientist, including Dr. Elliott, can precisely quantify the incidence of complications. For Defendants to claim this somehow makes Dr. Elliott's opinions unreliable is disingenuous at best.

As Dr. Elliott does make clear, the inability to quantify long-term complications caused by the TVT contrasts sharply with the absence of such complications in the autologous PVS and

Burch procedures. The products implanted in the latter procedures are fully absorbed by the body, thereby avoiding long-term problems. (Ex. 3 at 72:3-10; 73:1-74:18 (Burch); 75:17-76:11 (PVS)). Nevertheless, studies showing the safety of these products involved follow-up of 10 years. (Ex. 3 at 63:25-64:7 (PVS); 64:23-66:19 (Burch)). Dr. Elliott's own experience reveals the absence of any long-term complications – an opinion he holds to a reasonable degree of medical certainty. (Ex. 3 at 325:8-326:7). In fact, Dr. Elliott has never seen a woman with severe pain from the autologous PVS or Burch procedure; he sees women with such pain from the TVT weekly. (Ex. 3 at 327:14-328:5).

B. Despite Defendants' claims, Dr. Elliott reviewed and discussed available position papers – including AUGS, AUA and Cochrane.

Defendants claim that Dr. Elliott disregarded or ignored available position papers and various organizations' analyses related to TVTs. This is false. Dr. Elliott reviewed, analyzed and, in some instances, disagreed with the conclusions of various professional societies. In each instance, Dr. Elliott provided the reasons and scientific support for doing so.

For example, Dr. Elliott has read and carefully considered the AUGS/SUFU statements on mid-urethral slings (one of which is the TVT). (Ex. 3 at 138:23-25). In fact, he is a member of SUFU and regularly attends meetings of AUGS. (Ex. 3 at 139:1-7). He has taken and passed the AUGS examination on mid-urethral slings, the Burch colosuspension procedure and autologous pubovaginal slings. (Ex. 3 at 139:14-140:12). Regardless of Defendants' characterization, the AUGS/SUFU statements are based on product efficacy, and Dr. Elliott's opinions focused on the products' long-term complications. (Ex. 3 at 117:6-118:7; 126:11-127:20). He explains his disagreement with the safety statements in the papers. (Ex. 3 at 142:17-143:14; 147:16-23). In fact, he outlines in detail precisely which parts of the paper are accurate and which are inaccurate. (Ex. 3 at 147:24-148:22). Further, Dr. Elliott has testified that he prefers to review and rely on the actual peer-reviewed studies and perform his own

comprehensive and detailed review of the articles rather than simply rely upon position papers put out by various organizations.

The Defendants imply that Dr. Elliott disregarded the Cochrane Review publication. (Memo at 7). Dr. Elliott explains in great detail his criticisms of the methods used in the Cochrane Review and also engaged in a rigorous and detailed analysis of the meta-analysis described in the Cochrane Review. As Dr. Elliott testified, the fact that a meta-analysis involves multiple studies does not make it sacrosanct, particularly where the included studies all suffer from serious methodological defects, as in this instance. A review of poor studies generates unreliable results. (Ex. 3 at 60:23-62:1).

Even the Cochrane Review authors acknowledge that the quality of studies analyzed was, at best, moderate. (*Id.*). The authors agree that long-term data is unavailable and needed. (Ex. 3 at 90:8-11). Dr. Elliott, after reviewing the underlying studies, found the included studies to be of low quality for the reasons he carefully articulated. (Ex. 3 at 63:11-21; 69:22-70:2; *see* text, *infra*). For example, Dr. Elliott opined the studies are not generalizable because they involved highly skilled, experienced surgeons, who will rarely be the ones performing the commonplace TVT implantations. In his expert opinion, this expertise caused a dramatic understatement of the complications ordinarily experienced. While the Cochrane Review focused on efficacy and not complications (the latter being the key issue) (Ex. 3 at 106:10-22), even the Cochrane Review acknowledged that the TVT causes greater bladder perforations than traditional SUI treatment procedures. (Ex. 3 at 188:16-189:13). All of these concerns were expressed and explained by Dr. Elliott when he was questioned about this review. (Ex. 3 at 196:15-197:4; 199:11-201:16).

C. Dr. Elliott considered all available data and did not cherry-pick studies.

Defendants next argue that Dr. Elliott cherry-picked which studies to review and only considered the studies that were most supportive of his opinion and disregarded those that were not. Specifically, Defendants state that Dr. Elliott "achieved the conclusion that he wants to

achieve by cherry-picking favorable portions of certain papers while arbitrarily rejecting unfavorable portions of those same papers." (Memo at 7). This is a false assertion.

When confronted with the data upon which Defendants rely, Dr. Elliott repeatedly and with great detail explained the studies' shortcomings and why they did not alter his opinions. For example, when discussing the AUA paper Dr. Elliott noted that it focused on efficacy studies, not complications. (Ex. 3 at 116:2-11). He agreed with its conclusion that the TVT is the most commonly used device and is effective in treating SUI. And he agreed with the conclusion that the TVT reduces the surgical time involved in implantation. But he rejected the notion that TVT has fewer complications. (Ex. 3 at 118:1-119:23). He provided support and evidence for this conclusion in both his report and his deposition testimony.

Defendants also correctly note that this Court has excluded opinions when the expert failed to account for contrary scientific literature. (Memo at 7) (*citing Winebarger*, 2015 WL 1887222 at *8). But in this case, Dr. Elliott addressed in detail all contrary literature Defendants cited and explained why the articles do not alter his opinions. This is precisely what occurred in the Cook litigation, where the Court rejected the same attack on Dr. Elliott's opinions. The Court initially noted that it had excluded testimony in previous opinions only when the expert rejected the studies "without *any* scientific basis for doing so." *Hovey*, 2015 WL 1405565 at *10 (*citing Tyree v. Boston Scientific Corp.*, No. 2:12-cv-08633, at *7 (S.D.W. Va. Oct. 20, 2014) (emphasis in original)). Dr. Elliott has provided ample basis for not relying on the articles Defendants cite.[3] Further, in *Hovey*, this Court held that "whether Dr. Elliott failed to review these particular articles goes to the weight of his testimony, not its admissibility." *Hovey*, 2015 WL 1405565 at *10; *see also Watkins*, 2015 WL 1395773 at *10 (same).

[3] Defendants claim Dr. Elliott ignored the Heinonen study (Memo at 6). However, this study was on Dr. Elliott's reliance list and the only reason he did not discuss it in his deposition is Defendants refusal to provide him with a copy of the article when he asked to see it. (Ex. 3 at 329:11-21). The notion that an expert must have instant recall of every article by name finds no support in either *Daubert* or logic.

D. Dr. Elliott properly relies upon his own surgical experiences.

Defendants argue that this Court should exclude testimony based on Dr. Elliott's "personal experiences" as it has done with other experts in the past. (Memo at 7-8). This Court has never held that a physician's own experience in practice is inadmissible or unreliable. Rather, in the principal case Defendants cite, the Court held that personal experience cannot be the *sole* basis of the expert's opinion. *Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222 at *8 (S.D. W. Va. Apr. 24, 2015) (*cited in* Memo at 8).[4] Most recently, in its *Cook* opinions, this Court rejected a similar attack by plaintiffs against a defense expert. In those cases, the Court held that personal experiences may serve as the basis for expert testimony, so long as the expert explains how his experiences lead to the opinion. In particular, the Court found the expert's testimony tying his results to a corroborating article to be sufficient. *Hovey v. Cook, Inc.*, No. 2:13-cv-18900, 2015 WL 1405565, at *13, 16 (S.D. W. Va. Mar. 26, 2015); *Watkins v. Cook, Inc.*, No. 2:13-cv-20370, 2015 WL 1395773, at *13, 16 (S.D. W. Va. Mar. 25, 2015).

In this case, Dr. Elliott cites a plethora of literature backing up the results of his own surgical practice and ties his experiences to the particular findings of numerous studies on synthetic mesh, including studies on the TVT specifically. Among the TVT analyses Dr. Elliott cites are those by Wang (infections, erosions, exposures and contractions) (Ex. 3 at 192:13-193:13), Klinge, Klosterhalfen, Costello and Clave (Ex. 3 at 165:15-166:8).

Dr. Elliott reviewed, relied upon and discussed all available studies and data. In each instance he provided scientific support for his opinions and conclusions – regardless of whether he agreed or disagreed with the authors' conclusions. Dr. Elliott relied upon his professional surgical and medical training and experience as allowed by this Court. These are all acceptable

[4] In the other case cited by Defendants, this Court did not reject clinical experience testimony, but rather found the expert's description of his clinical experience to be unreliable because his conclusions were a moving target, changing from time to time, case to case, thus demonstrating the lack of reliable methodology. *In re Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 606 (S.D. W. Va. 2013) (*cited in* Memo at 8).

components of Dr. Elliott's methods and Defendants' Motion should be denied.

III. Dr. Elliott's Opinions Regarding The Dangerous Components of Mesh Devices Should Be Allowed Because They Are Well Grounded in Evidence and in Law.

The Defendants assert that Dr. Elliott is offering device *design* opinions in this matter simply because he states other synthetic mesh devices offer safer alternatives. In their Memo, Defendants state that there "is nothing about Dr. Elliott's background, training, and experience as a urologist that would make him qualified to offer product design opinions." (Memo at 8). However, making a determination that one product is safer than another based on inherent principles of a product does not automatically translate into an expert opinion on the actual design of a medical device.

A. Dr. Elliott is qualified to offer the opinions he has expressed.

Defendants assert that there is "nothing about Dr. Elliott's background, training and experience as a urologist would make him qualified to offer product design opinions." (Memo at 8). This is simply untrue. As this Court previously found, Dr. Elliott is an experienced and qualified surgeon who is an expert and can testify about the components of polypropylene mesh, the complications resulting from the mesh and safer design alternatives. Additionally, Dr. Elliott has published scientific manuscripts and dozens of peer-reviewed articles discussing the very design issues the Defendants claim he is unqualified to opine about. As this Court previously held:

> Dr. Elliott has personally treated patients with Prolift mesh complications "too numerous to count." (Elliott Dep. [Docket 116-2], at 178). He has published nearly 60 peer-reviewed articles and given over 100 lectures pertaining to POP. (Elliott Report [Docket 116-1], at 2). Additionally, he has published two scientific manuscripts dealing specifically with polypropylene mesh. (*Id.*). According to Dr. Elliott, his "practice has become increasingly dedicated to treating a whole host of life-altering complications associated with the use of both SUI and POP meshes, including meshes made by Ethicon."

Bellew v. Ethicon, Inc., No. 13-cv-22473, Mem. Op. & Order, Dkt. No. 265, at pp. 23 (Nov. 20, 2014). Dr. Elliott's substantial clinical experience, his study and review of the vast scientific

literature, and his peer-reviewed publication history give him the knowledge and expertise necessary to opine about the design of the mesh, the complications that arise with the use of the mesh and the safer alternatives to polypropelene mesh. Defendants' Motion should be denied.

B. Dr. Elliott's testimony properly explains the superiority of other synthetic products, notwithstanding his claim that synthetic products overall are inferior.

In its Motion, Defendants state that Dr. Elliott should not be permitted to suggest that other mesh products offer a safer alternative to the TVT mesh products. (Memo at 9). Admittedly, Dr. Elliott is not an advocate for any synthetic mesh finding all of them to pose inherent dangers. But that general opinion does not detract from the reliability of his testimony that products configured differently than Defendants' products are safer. *See Nease v. Ford Motor Co.* Civ. Act. No. 3:13-29840, 2015 WL 4508691, at *5 (S.D.W. Va. July 24, 2015) (Chambers, J.) ("If a product can be made safer and the danger may be reduced by an alternative design at no substantial increase in price, then the manufacturer has a duty to adopt such a design."). Indeed, an alternative design must only be a "safer alternative." "It need not eliminate all potential risks to be safer." *Thomas v. CMI Terex Corp.*, Civ. No. 07-3597 (JBS/KMW), 2009 WL 3068242, at *16 n. 15 (D.N.J. Sept. 21, 2009). The alternative must "not be as unsafe" as the product at issue, not "safe" in the abstract. *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 573 (E.D. Pa. 2011) (*cited in* Memo at 9-10).

In support of their argument, Defendants cite to this Court's decision in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691 (S.D.W. Va. 2014) (Memo at 9). According to Defendants, the Court excluded expert testimony on the superiority of laser-cut mesh over mechanical-cut for two reasons: because the testimony was unreliable and because the expert could not testify to a reasonable degree of medical certainty that the laser cut was a safer method. *Id.* at 712-13. Employing that argument here is misleading at best. The sole ground of the Court's decision was the unwillingness of the expert to say that laser cut products are safer *to a reasonable degree of*

medical certainty, which the Court found made the testimony unreliable. *Id.* Here, Dr. Elliott's opinions on various alternative synthetic mesh designs, cuts and tensioning being safer than Defendants' products are made to a reasonable degree of medical certainty. (Ex. 1 at 3). Dr. Elliott simply believes that all synthetic mesh products and tensioning pose some risks – but, different levels of risk. This opinion is not inconsistent with this Court's and other courts' rulings. Defendants' Motion should be denied.

C. Dr. Elliott's opinions concerning lighter weight/larger pore size mesh are reliable.

Defendants argue that Dr. Elliott is not qualified opine that lighter weight, larger pore size mesh is less dangerous because he has no expertise in biomaterials or polymers (and has not conducted any studies himself). (Memo at 10). A physician is competent to determine the adverse effects of a medical drug or device based on his own observations in practice and his reading of studies and medical literature, notwithstanding that he may not be experienced in designing, engineering, constructing or marketing such a drug or device.

Dr. Elliott cites extensive data from multiple studies showing that lighter weight/larger pore size mesh leads to fewer complications, including less chronic pain, less contraction, less shrinkage, less foreign body reaction, and less folding of the mesh. (Ex. 3 at 240:20-241:5; 273:13-25; Ex. 1 at 16-18, 20). Ethicon's own personnel agree that lighter weight/larger pore mesh reduces complications (Ex. 3 at 274:1-13), as do Ethicon's internal documents (Ex. 3 at 238:14-239:13; Ex. 1 at 16). Dr. Elliott's report explains in detail why the heavier weight, smaller pore mesh used in TVT causes the cascade of complications resulting in life-altering harm to a woman. (Ex. 1 at 16-21).

Defendants further argue that the studies Dr. Elliott cites involve treatment of hernia and prolapse, not SUI. (Memo at 10). But as Dr. Elliott explains, extrapolation of these results is appropriate for SUI treatment given that the mesh used in the TVT is identical to the hernia mesh, the vagina is subject to all the same forces as the abdominal area (and even additional

forces), and the vagina is subject to far greater infection. Notably, the medical literature (in particular, analyses by Drs. Klosterhalfen and Klinge) and Ethicon's own documents establish that complications would more likely than not be reduced if the mesh used in SUI treatment were lighter weight and had larger pore size. (Ex. 3 at 323:15-324:6).

Finally, Defendants assert that Dr. Elliott cannot establish that lighter weight/larger pore meshes are efficacious. (Memo at 10-13). Again, as Dr. Elliott testifies, this type of mesh has been effective where studied, which involves the treatment for hernias and pelvic organ prolapse. (Ex. 3 at 238:14-240:19). Even if there were some decrease in efficacy (which has not been established), Dr. Elliott holds the opinion that the alleviation of the risks involved in the small pore/heavy weight mesh would far outweigh any decrease in efficacy. (Ex. 1 at 18).

Dr. Elliott's opinions regarding the components and attributes of the mesh, and the complications that are experienced as a result, are based upon review of vast amount of literature, reliance upon other experts' opinions, review of internal Ethicon documents and his own personal surgical and publication experience. These opinions, and the methods Dr. Elliot used to reach these opinions, are reliable and his testimony on these opinions should be permitted.

IV. Dr. Elliott's Opinions Concerning Mechanical Cut vs. Laser Cut Are Reliable.

Defendants have attempted to make a circular argument related to Dr. Elliot's opinions that both mechanically cut and laser cut mesh are dangerous products. Defendants state that Dr. Elliot should not be allowed "to criticize mechanically-cut mesh or vice-versa. Dr. Elliot criticizes TVT mesh that is cut mechanically, but then criticizes the alternative method to cut with a laser." (Memo at 13). Dr. Elliott has testified that synthetic mesh is harmful no matter how it is cut, and his opinions are based on sufficient evidence. (Ex. 3 at 226:20-24). Dr. Elliott has also testified that laser cutting reduces the risks of mechanical cutting, even though it does not eliminate those risks. As explained in Dr. Elliott's report, laser cutting introduced new and

different risks. (Ex. 1 at 28). As shown above, the safer alternative design must only be "safer," not "safe in the abstract."

Regarding support for his opinion, Dr. Elliott's indictment of mechanical cutting as leading to fraying, roping, particle loss and inflammation is based on the papers he has reviewed, his discussions with colleagues at international meetings, Ethicon's own internal documents that consistently concede these effects, and Dr. Elliott's clinical experience in which he has seen these complications in practice. (Ex. 3 at 226:25-227:16; 228:6-18). These materials are cited extensively in his expert report. (Ex. 1 at 21-24).

In his report and deposition testimony, as well as his publications, Dr. Elliott clearly states all transvaginal mesh is unsafe. The difference in how the mesh is cut does not substantially alter the product to make it safe and Defendants' attempts at conflating Dr. Elliott's opinions should not be allowed. Their Motion should be denied.

V. Defendants Misconstrue Dr. Elliott's Actual Opinions Related to the Duties of a Medical Device Manufacturer.

A. Dr. Elliott is qualified to opine on Ethicon's research and testing as it relates to his knowledge and expertise.

Defendants assert that Dr. Elliott should not be allowed to testify about the level of testing that Ethicon should have performed. They state that Dr. Elliott "is unable to identify a single rule or regulation that would require Defendants to conduct different testing." (Memo at 16). There is apparently a misunderstanding about his opinions on this issue. Dr. Elliott has no intention to opine on the *legal adequacy* of the testing conducted by Ethicon, but rather on the *factual* underpinnings of whether nor not testing was conducted. In Dr. Elliott's review of the literature and internal Ethicon documents, he observed that Ethicon, when confronted with safety issues, did not conduct testing. Dr. Elliott does not intend to offer an opinion that there was some legal or regulatory violation that arose from Ethicon's lack of testing, but rather the factual and undisputed point that, when safety issues arose, Ethicon did not conduct testing. For

example, when Ethicon received reports of degradation of their mesh products, they did not conduct testing to determine whether or not this was actually occurring or what complications were arising as a result. The opinion Dr. Elliott holds is related to the safety of the device, not the legal or regulatory requirements surrounding a medical device manufacturer's duty to test. Dr. Elliott should be permitted to state the facts upon which he relied in determining the scope and prevalence of certain complications associated with polypropelene mesh products. The fact that none of the studies he relies upon originated from Ethicon, because there were no studies conducted, is a fact that is relevant to the question of safety of these devices, not to the regulatory or legal requirements related to testing.

Moreover, Dr. Elliott is more than qualified to opine on testing that was or was not conducted by a medical device or pharmaceutical company. Over the course of his career, Dr. Elliott has reviewed hundreds of journal articles, has published more than 60 times in peer-reviewed publications and has been an investigator on seven studies sponsored by industry. Dr. Elliott is not seeking to opine on the adequacy of the testing done by Ethicon – but merely on the lack of testing from a factual standpoint and how that impacted his opinions. This does not require regulatory nor legal experience.

Further, the issue raised by Defendants related to the legal conclusions or regulatory standards is not an issue to be decided under the *Daubert* standard. This question is more properly addressed with a motion in limine or at trial. Defendants' Motion should be denied.

B. Dr. Elliott is qualified to opine on the adequacy of the IFU related to adverse events.

Defendants argue that Dr. Elliott is not qualified to render opinions about regulatory matters or the FDA – including their assertion that Dr. Elliott "has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert opinions regarding the standard of care for collecting and reporting adverse events." (Memo at 17). At no

point has Dr. Elliott held himself out as an FDA or regulatory expert, nor does he opine on the collecting or reporting of adverse events. Dr. Elliott's opinions and testimony relate to how accurately the IFU discloses the known risks to the surgeons implanting these devices.

In his reports, Dr. Elliott spends considerable amount of time explaining and discussing the support he has for his opinion that the IFU does not adequately warn physicians or patients of the known risks of the device or the procedure. For example, Dr. Elliott states "IFU is silent of the fact that over-tensioning can cause other adverse reactions as well, including vaginal or urethral erosion." (Ex. 1 at 32). As a surgeon who uses these types of products, who has repeatedly seen these complications and who has published numerous times on the subject, Dr. Elliott is qualified to opine about how accurate and complete the warnings and adverse events listed in the IFU are to the implanting surgeons. He is not, and will not, offer opinions or testimony about the FDA regulations or the process of collecting and reporting adverse events to the FDA. However, Dr. Elliot is qualified to discuss how the warnings in the IFU reflect the known data and should be permitted to do so.

C. Dr. Elliott is qualified to offer opinions on the adequacy of the IFU on implantation information and training techniques.

Ethicon has asserted that Dr. Elliott should not be permitted to opine on the shortcomings of Ethicon's training programs because this somehow amounts to opining on corporate conduct. Defendants state that Dr. Elliott is "not qualified to opine about the level of training that a manufacturer is required to provide." (Memo at 17). However, when examining what Dr. Elliott actually discusses related to the training and implantation information in the IFU, it is clear he is discussing these issues from a surgical perspective – a perspective the jury would not otherwise have. This testimony clearly falls within the bounds of expert testimony and his expertise. Dr. Elliott opines as follows:

> The IFU's Adverse Reactions section says that over correcting, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract

> obstruction, yet the surgeon has been previously provided with five conflicting and confusing instructions to place the tape with (1) minimal tension, (2) tension-free, (3) loosely, (4) without tension, and (5) to adjust the tail of the TVT mesh until leakage is limited. **This leaves the physician with no clear, articulable standard on how to avoid the serious adverse reaction of urinary retention or urinary obstruction.**

(Ex. 1 at 31-32 (emphasis added)). Similarly, in his Prolift report, Dr. Elliott discusses the adequacy of the IFU as it relates to the surgical perspective and the practical impact it has on the implanting surgeon. He opines as follows:

> Hydrodissection is a surgical step used to create a space between the vagina and the rectum and/or bladder. The purpose of this step is to identify and surgically enter the rectovaginal/vesicovaginal space more easily and to reduce the risk of injury to the adjacent rectum and/or bladder. This step would seem even more important given the differences between vaginal dissections in Prolift procedures versus traditional procedures. However, the Prolift IFU makes no mention of vaginal wall hydrodissection.

(Ex. 2 at 42). Dr. Elliott is not offering expert opinions on the industry or company requirements on training – he is providing an expert opinion, one he is highly qualified to provide, related to the adequacy of the IFU and Ethicon's method of explaining the procedure to surgeons. Dr. Elliott should be permitted to discuss this and Defendants' Motion should be denied.

VI. Dr. Elliott's Testimony Regarding Problems with the TVT Mesh Are Reliable.

Defendants assert that Dr. Elliott should not be allowed to opine on the various components and attributes of the mesh device simply because he is not a biomaterials or polymer science expert. (Memo at 18). Dr. Elliott does not, and has not, held himself out to be a biomaterials expert. However, as noted below, this Court has already ruled on this issue and found Dr. Elliott qualified to testify about mesh degradation and other aspects of the mesh.

A. Dr. Elliott's opinions on degradation and cytotoxicity are reliable.

After apparently taking note of this Court's prior order on the subject, Defendants seemingly do not deny that Dr. Elliott may offer an expert opinion regarding mesh degradation. Rather, Defendants' only argument now is that Dr. Elliott does not sufficiently establish that

degradation leads to complications. (Memo at 18). This Court has already reviewed briefing on the issue of degradation and has resolved this dispute. Raising this argument again – with a slightly different twist – is a feeble attempt by the defense to reargue the points and ask the Court to reconsider its well-reasoned order. After careful consideration, this Court found as follows:

> The defendants argue that Dr. Elliott is unqualified to opine on mesh degradation and that his opinions are "unconnected to any reliable methodology." (Defs.' Mem. re: Elliott [Docket 117], at 11-15). With regard to his qualifications, the defendants contend that Dr. Elliott has no experience in the field of polymer science and has not shown that he possesses any specialized knowledge observing mesh degradation in his practice. (*Id.* at 13).
>
> An expert may be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all the details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). Dr. Elliott has personally treated patients with Prolift mesh complications "too numerous to count." (Elliott Dep. [Docket 116-2], at 178). He has published nearly 60 peer-reviewed articles and given over 100 lectures pertaining to POP. (Elliott Report [Docket 116-1], at 2). Additionally, he has published two scientific manuscripts dealing specifically with polypropylene mesh. (*Id.*). According to Dr. Elliott, his "practice has become increasingly dedicated to treating a whole host of life-altering complications associated with the use of both SUI and POP meshes, including meshes made by Ethicon." (*Id.*). Therefore, I **FIND** that Dr. Elliott is qualified to offer opinions on mesh degradation.
>
> With regard to his methodology, Dr. Elliott bases his opinions on both his clinical experience, as well as his extensive review of the scientific literature and internal Ethicon documents. Specifically, in the section of his report discussing mesh degradation, Dr. Elliott cites numerous peer-reviewed studies and articles to support his assertions. (*See* Elliott Report [Docket 116-1], at 34-35 (citing Costello and Clave in the text, to name a few)). Accordingly, I **FIND** that Dr. Elliott may testify regarding mesh degradation.

Bellew v. Ethicon, Inc., No. 13-cv-22473, Dkt. No. 265, at pp. 22-23 (Nov. 20, 2014).

Dr. Elliott's clinical experience with mesh patients is that degradation results in brittle, sharp mesh that cracks and breaks. (Ex. 3 at 244:24-245:21). The fact that explanted mesh is brittle or cracking, by definition, establishes degradation. (Ex. 3 at 249:17-23). The Clave study found surface cracking in nearly half (45 percent) of the explants studied. This degradation leads to the cascade of complications discussed above. (Ex. 3 at 253:16-254:6). Complications seen

more than six weeks after implant are likely products of degradation. (Ex. 3 at 257:13-258:21).

Despite Defendants assertion, Dr. Elliott has explained and supported his opinions related to degradation and the resulting complications. Further, this Court has already considered and addressed this supposition and that order should be upheld.

B. Dr. Elliott's opinions on shrinkage, contraction and tensioning are reliable.

Defendants argue that Dr. Elliott should not be allowed to render opinions on various other properties of mesh because the "medical literature he cites in support of this opinion address hernia mesh, not SUI or POP mesh." (Memo at 19). Dr. Elliott has made clear why it is appropriate to extrapolate the hernia data relating to the identical mesh to this context.

Defendants claim that Dr. Elliott acknowledged that different forces apply to the vagina than to the abdomen. (Memo at 19). Actually, in the excerpt cited, Dr. Elliott testified that the vagina has even more forces applied to it, meaning that mesh used to treat SUI would be subject to even more contraction. (Ex. 3 at 193:20-194:6). Furthermore, Defendants cut off much of Dr. Elliott's answer where he indicates that the vagina creates even more problems for mesh use, given the vagina's high bacterial contamination.

Defendants attack Dr. Elliott's opinion on shrinkage by claiming it is linked solely to the inability to properly tension the device, and Dr. Elliott is not qualified to so opine because he does not work with the TVT. (Memo at 19). Initially, Dr. Elliott cites other factors besides tensioning as causing contraction of Defendants' products, including foreign body reaction (Ex. 1 at 17, 18) and use of heavyweight/small pore mesh (Ex. 1 at 16). Further, Dr. Elliott is not unqualified to testify as to a product he has studied simply because he recognized immediately the hazards of the product and declined from the start to administer it surgically himself. Moreover, Ethicon's internal documents – documents upon which Dr. Elliott relies – are replete with issues regarding tensioning.

Dr. Elliott has extensively studied the properties of TVT mesh through literature reviews,

internal Ethicon documents, reviews of other expert reports, and extensive personal experience with surgical removal of the very devices at issue here. Defendants' Motion should be denied.

VII. This Court Has Already Held That Dr. Elliott's "Marketing" Opinions Are Proper.

Defendants have moved this Court to exclude Dr. Elliott's opinions related to marketing of the Prolift device, stating "Dr. Elliott should not be permitted to provide marketing opinions, such as making the highly inflammatory and improper assertion that 'I agree with Ethicon's 2012 decision to cease marketing the Prolift System for use in the United States.'" (Memo at 22). Much like other instances in their motion, the Defendants appear to be unfamiliar with this Court's prior orders. This Court previously held:

> The defendants contend that Dr. Elliott is unqualified to offer opinions on Ethicon's marketing of the Prolift. (Id. at 4). The plaintiff concedes that Dr. Elliott is not an expert in marketing and "true marketing opinions should be excluded." Nevertheless, I agree with the plaintiff that Dr. Elliott's statement that "the Prolift System should have never been marketed to surgeons or patients in the first place," addresses the Prolift's safety, and not the defendants' marketing techniques. (Elliott Report [Docket 116-1], at 3). Therefore, the defendants' motion with regard to marketing opinions is **DENIED as moot in part** and **DENIED in part**. To the extent that the defendants have further objections, they are free to raise them at trial.

Bellew v. Ethicon, Inc., No. 13-cv-22473, Mem. Op. & Order, Dkt. No. 265, at pp. 18-19 (Nov. 20, 2014). Plaintiffs simply request the Court adopt this same position on the motion at issue.

CONCLUSION

Dr. Elliott is qualified to testify in all areas of treatment of stress urinary incontinence in women as well as the use of synthetic and non-synthetic mesh in the human body. His opinions are properly based on his own clinical experience, his review of the relevant scientific literature, and his analysis of Defendants' documents and testimony. Dr. Elliot has explained in detail how he determined on which materials he would rely and not rely. Defendants' attacks on Dr. Elliott's opinions go to the weight of the testimony and not its admissibility. Defendants' motion should be denied in its entirety.

Dated May 10, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing amended document on May 10, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Joseph J. Zonies
Attorney for Plaintiffs